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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,254	07/31/2001	Daniel K. Recinella	ANGIO P-15 - (500622.2000)	3169
7590	07/19/2004		EXAMINER	
Lloyd McAulay, Esq. Reed Smith LLP 375 Park Avenue New York, NY 10152			SIRMONS, KEVIN C	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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TECHNOLOGY CENTER R3700

## Office Action Summary

Application No.

09/919,254

Applicant(s)

RECINELLA ET AL.

Examiner

Kevin C. Simons

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24 and 26-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-43 is/are allowed.
- 6) ☒ Claim(s) 24, 26, 44-46 and 48 is/are rejected.
- 7) ☒ Claim(s) 27-34 and 47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 26, 44-46 and 48 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Teirstein U.S. Pat. No. 5,533,978.

Teirstein discloses a method for supplying a contrast medium to a patient's vascular system comprising: providing a flexible bag filled with contrast medium at essentially atmospheric pressure (14); operatively connecting said flexible bag to the patient's vascular system (fig. 2) via a gas transfer system (10), said gas transfer system including: a dual check valve (16) adapted to be connected to a lower pressure source of contrast medium (fully capable of being adapted (see 20 connect to 14), said dual check valve having a first inlet port (top portion/input end of 42), a first outlet port (distal end/out end of 48) and a first inlet-outlet port (dual check valve portion of 16 connected to syringe (50)), said dual check valve containing a first one-way valve (42) at said first inlet port automatically responsive to the relatively low pressure at said first inlet-outlet port to permit downstream fluid flow and to prevent upstream fluid flow (col. 5, lines 1-19), said dual check valve containing a second one-way valve (48) at said first outlet port (distal portion of 48) automatically responsive to the relatively high pressure at said first inlet-outlet port to permit downstream fluid flow and to prevent upstream fluid flow

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(48), said first inlet-outlet port in communication with said first and second one-way valves and adapted to be connected to a pump (fig. 2), and a connecting tubular member (22) having an upstream and downstream end, said upstream end in communication with said first outlet port of said dual check valve; purging said gas transfer system of air (col. 5, lines 5-9) delivering said contrast medium from said flexible bag through said gas transfer system to the patient's vascular system (fig. 2), the delivering step including: suction at said first inlet-outlet port by the pump to cause said first one-way valve to automatically open (col. 7, lines 1-11), allowing flow of contrast medium from said bag into the pump (col. 7, lines 1-11), and to cause said second one-way valve to automatically close (col. 7, lines 1-11), preventing fluid flow upstream from said connecting tubular member into the pump, and exerting positive pressure at said first inlet-outlet port from the pump to cause said second one-way valve to automatically open, allowing fluid flow from said pump into said tubular member, and to cause said first one-way to automatically close, preventing upstream fluid flow to the source (col. 7, lines 7-11). However, it may not be clear to one of ordinary skill in the art that the valves disclosed by Teirstein could be automatically responsive to low and high pressures. It is nevertheless, the examiner's position that the valves of Teirstein are automatically responsive to low and high pressures (col. 4, lines 65-67 and col. 7, lines 11-13). In the aforementioned passages, Teirstein clearly teaches that his valves can be check valves, which are identical to the valves disclosed by applicant and that the valves can be ball valves. Both are well known in the art as being automatically responsive to various pressures. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Teirstein to have automatically responsive valves as taught by Teirstein (col. 4, lines 65-67 and col. 7, lines 11-13) to control the flow of

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contrast medium (col. 4, lines 65-67); as to claim 26, (56); as to claim 44, (col. 6, lines 59-67 and col. 7, 1-17); as to claim 45, (see above rejection and a tubular member having an upstream end connected to the outlet port and a down stream end connectable to a catheter (col. 4, lines 53-54); as to claim 46, (col. 4, lines 53-54 and col. 7, lines 16-17); and as to claim 48, (see above rejections).

### ***Allowable Subject Matter***

Claims 27-34 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 35-43 are allowable over the prior art of record.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record disclose the device substantially as claimed at the time the invention was made except for a third one-way valve in communication with said downstream end of the tubular member to permit downstream fluid flow from the tubular member and to prevent upstream fluid flow in said tubular member.

### ***Response to Amendment***

#### ***Drawings***

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: The gas transfer system mentioned in the specification does not have a reference numeral.

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Applicant's proposed drawing correction, corrected drawings, and/or amendment to the specification to add the reference sign(s) in the description, are acceptable. Therefore, the objection has been withdrawn.

### ***Response to Arguments***

Applicant's arguments with respect to claims 24 and 26-48 have been considered but are moot in view of the new ground(s) of rejection.

Basically, Teirstein discloses various types of valves including, manual valves check valves and ball valves, which can all be used in his invention at the users discretion. It is well known in the art that check and ball valves work automatically as clearly disclosed in applicant's specification. That is clearly why applicant uses check valves.

Applicant has taken the word typically to mean that the manifold would always have extra valves. However, typically does not mean always and could include sometimes, occasionally or not at all. Therefore, it may not be necessary to have extra valves 44 and 46. Additionally, even if the valves were present at the time, Teirstein did not indicate that they were in use. Therefore, there would be no fluid flow from in connection to the valves, which would contaminate the closed system of Teirstein. Accordingly, Teirstein disclosed the claimed invention.

Moreover, Teirstein clearly discloses the drawing step which includes "to cause said first one-way valve to automatically open (see above rejection), allowing flow of contrast medium from said bag into the pump, and to cause said second one-way valve to automatically close,

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preventing fluid flow upstream from said connecting tubular member into the pump” and vice versa (see above rejection; emphasis added).

As to applicant response that the Examiner on page 4 and 5 (response to arguments) appears to suggest that such a precise interaction between the two valves is well known, it is the examiner’s position that the valves are well known and that Teirstein teaches using the valves as disclosed by applicant. Furthermore, applicant and Teirstein valves are structurally identical since applicant has not given any structure to his valve and there is no reason why the valves of Teirstein would not perform the same as applicant’s valves. The evidence to support the examiner’s rational is clearly supported in Teirstein and the fact the applicant again (emphasis added) uses the same valve as Teirstein. There is no evidence in Teirstein that would indicate that the valves would not perform like the valves of applicant.

### ***Conclusion***

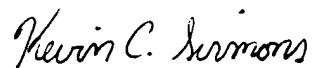
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

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In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

A handwritten signature in cursive script that reads "Kevin C. Sirmons".

Kevin C. Sirmons  
Patent Examiner  
7/7/04



# USPTO TO PROVIDE ELECTRONIC ACCESS TO CITED U.S. PATENT REFERENCES WITH OFFICE ACTIONS AND CEASE SUPPLYING PAPER COPIES

In support of its 21<sup>st</sup> Century Strategic Plan goal of increased patent e-Government, beginning in June 2004, the United States Patent and Trademark Office (Office or USPTO) will begin the phase-in of its E-Patent Reference program and hence will: (1) **provide downloading capability of the U.S. patents and U.S. patent application publications cited in Office actions** via the E-Patent Reference feature of the Office's Patent Application Information Retrieval (PAIR) system; and (2) **cease mailing paper copies of U.S. patents and U.S. patent application publications with Office actions** (in applications and during reexamination proceedings) except for citations made during the international stage of an international application under the Patent Cooperation Treaty (PCT). In order to use the new E-Patent Reference feature applicants must: (1) obtain a digital certificate and software from the Office; (2) obtain a customer number from the Office; and (3) properly associate patent applications with the customer number. Alternatively, copies of all U.S. patents and patent application publications can be accessed without a digital certificate from the USPTO web site, from the USPTO Office of Public Records, and from commercial sources. The Office will continue the practice of supplying paper copies of foreign patent documents and non-patent literature with Office actions. Paper copies of cited references will continue to be provided by the USPTO for international applications during the international stage.

## Schedule

June 2004	TCs 1600, 1700, 2800 and 2900
July 2004	TCs 3600 and 3700
August 2004	TCs 2100 and 2600

All U.S. patents and U.S. patent application publications are available on the USPTO web site. However, a simple system for downloading the cited U.S. patents and patent application publications has been established for applicants, called the E-Patent Reference system. As E-Patent Reference and Private PAIR require participating applicants to have a customer number, retrieval software and a digital certificate, all applicants are strongly encouraged to contact the Patent Electronic Business Center to acquire these items. To be ready to use this system by June 1, 2004, contact the Patent EBC as soon as possible by phone at 866-217-9197 (toll-free), 703-305-3028 or 703-308-6845 or electronically via the Internet at [ebc@uspto.gov](mailto:ebc@uspto.gov).

## **Other Options**

The E-Patent Reference function requires the applicant to use the secure Private PAIR system, which establishes confidential communications with the applicant. Applicants using this facility must receive a digital certificate, as described above. Other options for obtaining patents which do not require the digital certificate include the USPTO's free Patents on the Web program (<http://www.uspto.gov/patft/index.html>). The USPTO's Office of Public Records also supplies copies of patents for a fee (<http://ebiz1.uspto.gov/oems25p/index.html>). Commercial sources also provide U.S. patents and patent application publications.

*For complete instructions see the Official Gazette Notice, USPTO TO PROVIDE ELECTRONIC ACCESS TO CITED U.S. PATENT REFERENCES WITH OFFICE ACTIONS AND CEASE SUPPLYING PAPER COPIES, on the USPTO web site.*

## **NOTICE OF OFFICE PLAN TO CEASE SUPPLYING COPIES OF CITED U.S. PATENT REFERENCES WITH OFFICE ACTIONS, AND PILOT TO EVALUATE THE ALTERNATIVE OF PROVIDING ELECTRONIC ACCESS TO SUCH U.S. PATENT REFERENCES**

### **Summary**

The United States Patent and Trademark Office (Office or USPTO) plans in the near future to: (1) cease mailing copies of U.S. patents and U.S. patent application publications (US patent references) with Office actions except for citations made during the international stage of an international application under the Patent Cooperation Treaty and those made during reexamination proceedings; and (2) provide electronic access to, with convenient downloading capability of, the US patent references cited in an Office action via the Office's private Patent Application Information Retrieval (PAIR) system which has a new feature called "E-Patent Reference." Before ceasing to provide copies of U.S. patent references with Office actions, the Office shall test the feasibility of the E-Patent Reference feature by conducting a two-month pilot project starting with Office actions mailed after December 1, 2003. The Office shall evaluate the pilot project and publish the results in a notice which will be posted on the Office's web site ([www.USPTO.gov](http://www.USPTO.gov)) and in the Patent Official Gazette (O.G.). In order to use the new E-Patent Reference feature during the pilot period, or when the Office ceases to send copies of U.S. patent references with Office actions, the applicant must: (1) obtain a digital certificate from the Office; (2) obtain a customer number from the Office, and (3) properly associate applications with the customer number. The pilot project does not involve or affect the current Office practice of supplying paper copies of foreign patent documents and non-patent literature with Office actions. Paper copies of references will continue to be provided by the USPTO for searches and written opinions prepared by the USPTO for international applications during the international stage and for reexamination proceedings.

### **Description of Pilot Project to Provide Electronic Access to Cited U.S. Patent References**

On December 1, 2003, the Office will make available a new feature, E-Patent Reference, in the Office's private PAIR system, to allow more convenient downloading of U.S. patents and U.S. patent application publications. The new feature will allow an authorized user of private PAIR to download some or all of the U.S. patents and U.S. patent application publications cited by an examiner on form PTO-892 in Office actions, as well as U.S. patents and U.S. patent application publications submitted by applicants on form PTO/SB08 (1449) as part of an IDS. The retrieval of some or all of the documents may be performed in one downloading step with the documents encoded as Adobe Portable Document format (.pdf) files, which is an improvement over the current page-by-page retrieval capability from other USPTO systems.

## Steps to Use the New E-Patent Reference Feature During the Pilot Project and Thereafter

Access to private PAIR is required to utilize E-Patent Reference. If you don't already have access to private PAIR, the Office urges practitioners, and applicants not represented by a practitioner, to take advantage of the transition period to obtain a no-cost USPTO Public Key Infrastructure (PKI) digital certificate, obtain a USPTO customer number, associate all of their pending and new application filings with their customer number, install no-cost software (supplied by the Office) required to access private PAIR and E-Patent Reference feature, and make appropriate arrangements for Internet access. The full instructions for obtaining a PKI digital certificate are available at the Office's Electronic Business Center (EBC) web page at: <http://www.uspto.gov/ebc/downloads.html>. Note that a notarized signature will be required to obtain a digital certificate.

To get a Customer Number, download and complete the Customer Number Request form, PTO-SB125, at: <http://www.uspto.gov/web/forms/sb0125.pdf>. The completed form can then be transmitted by facsimile to the Electronic Business Center at (703) 308-2840, or mailed to the address on the form. If you are a registered attorney or patent agent, then your registration number must be associated with your customer number. This is accomplished by adding your registration number to the Customer Number Request form. A description of associating a customer number with an application is described at the EBC web page at: [http://www.uspto.gov/ebc/registration\\_pair.html](http://www.uspto.gov/ebc/registration_pair.html).

The E-Patent Reference feature will be accessed using a new button on the private PAIR screen. Ordinarily all of the cited U.S. patent and U.S. patent application publication references will be available over the Internet using the Office's new E-Patent Reference feature. The size of the references to be downloaded will be displayed by E-Patent Reference so the download time can be estimated. Applicants and registered practitioners can select to download all of the references or any combination of cited references. Selected references will be downloaded as complete documents as Adobe Portable Document Format (.pdf) files. For a limited period of time, the USPTO will include a copy of this notice with Office actions to encourage applicants to use this new feature and, if needed, to take the steps outlined above in order to be able to utilize this new feature during the pilot and thereafter.

During the two-month pilot, the Office will evaluate the stability and capacity of the E-Patent Reference feature to reliably provide electronic access to cited U.S. patent and U.S. patent application publication references. While copies of U.S. patent and U.S. patent application publication references cited by examiners will continue to be mailed with Office actions during the pilot project, applicants are encouraged to use the private PAIR and the E-Patent Reference feature to electronically access and download cited U.S. patent and U.S. patent application publication references so the Office will be able to objectively evaluate its performance. The public is encouraged to submit comments to the Office on the usability and performance of the E-Patent Reference feature during the pilot. Further, during the pilot period registered practitioners, and applicants not represented by a practitioner, are encouraged to experiment with the feature, develop a proficiency in using the feature, and establish new internal processes for using the new access to the cited U.S. patents and U.S. patent application publications to prepare for the anticipated cessation of the current Office practice of supplying copies of such cited

references. The Office plans to continue to provide access to the E-Patent Reference feature during its evaluation of the pilot.

### Comments

Comments concerning the E-Patent Reference feature should be in writing and directed to the Electronic Business Center (EBC) at the USPTO by electronic mail at [eReference@uspto.gov](mailto:eReference@uspto.gov) or by facsimile to (703) 308-2840. Comments will be posted and made available for public inspection. To ensure that comments are considered in the evaluation of the pilot project, comments should be submitted in writing by January 15, 2004.

Comments with respect to specific applications should be sent to the Technology Centers' customer service centers. Comments concerning digital certificates, customer numbers, and associating customer numbers with applications should be sent to the Electronic Business Center (EBC) at the USPTO by facsimile at (703) 308-2840 or by e-mail at [EBC@uspto.gov](mailto:EBC@uspto.gov).

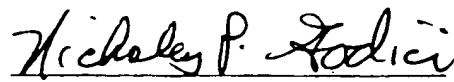
### Implementation after Pilot

After the pilot, its evaluation, and publication of a subsequent notice as indicated above, the Office expects to implement its plan to cease mailing paper copies of U.S. patent references cited during examination of non provisional applications on or after February 2, 2004; although copies of cited foreign patent documents, as well as non-patent literature, will still be mailed to the applicant until such time as substantially all applications have been scanned into IFW.

### For Further Information Contact

Technical information on the operation of the IFW system can be found on the USPTO website at <http://www.uspto.gov/web/patents/ifw/index.html>. Comments concerning the E-Patent Reference feature and questions concerning the operation of the PAIR system should be directed to the EBC at the USPTO at (866) 217-9197. The EBC may also be contacted by facsimile at (703) 308-2840 or by e-mail at [EBC@uspto.gov](mailto:EBC@uspto.gov).

Date. 12/1/03

  
Nicholas P. Godici  
Commissioner for Patents

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